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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,431	01/03/2007	Gerhard Tivig	PHDE030358US	9506

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EXAMINER	
BITAR, NANCY	

ART UNIT	PAPER NUMBER
2624	

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03/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/595,431	TIVIG ET AL.	
	Examiner	Art Unit	
	NANCY BITAR	2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/13/2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-6,12,14-22 and 24-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *2-6,12,14-22 and 24-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 April 2006* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's response on 1/13/2009 to the last Office Action, filed 12/23/2008, has been entered and made of record.

2. Claims 2-6, 12, 14-22 and 24-26 are currently pending.

3. Applicant arguments filed 1/13/2009 have been considered and are persuasive. Therefore, the rejection has been withdrawn.

Claim Objections

4. Claim 24 objected to because of the following informalities: the word " minotiring" is spelled wrong .Please fix it to monitoring. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 2-6; 20-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed

invention. There is no teaching in the specification that teaches a histogram including a continuously updates series of histogram value indication a current histogram value and a plurality of preceding histogram values are generated. The closest explanation in the specification :

[0032]..... *A readout of a histogram and a cumulative curve, in which the objects displayed on a viewing screen are dynamically updated in real time; an instantaneous marker that displays the actual measured value in the histogram and, consequently, also in the context of the statistical distribution.....*

Appropriate correction is required.

7. Claims 24-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no teaching in the specification that teaches the histogram and the cumulative curve are displayed superimposed with common axes and scaled and that the cumulative curve includes the sum of the medical measurement values the closest teaching the specification is paragraph [0030]. Appropriate correction is required.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject

matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 2-6, 12, 14-22, 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seely et al (US 2003/0117296) in view of Mika et al (US 2001/0031925).

As to claim 5, Seely et al teaches the method of automatically displaying medical measurement data in which a computer: receives the medical measurement data (107, figure 1) automatically converts in real time the received measurement data into data for a histogram including a continuously updated series of histogram values indication a current histogram value and a plurality of preceding histogram values are generated , (paragraph [0075], [0085]), during the conversion, generates a cumulative curve indication of the medical measurement data the cumulative curve being cumulative of the series of histogram values (figure 5, and 6) and outputs the cumulative curve combined with the histogram as picture signals (paragraph [0088-0089]). While Seely et a meets a number of the limitations of the claimed invention, as pointed out more fully above, Seely teaches the variability display (paragraph [0085-0090] but fails to specifically teach generating a cumulative curve indicative of the medical measurement data the cumulative curve being cumulative of the updated series of histogram values. Mika teaches a method for obtaining from a patient's heart data useful for on-line (i.e. real time) setting of the parameters of a detection time window in an excitable tissue control device. The method includes applying electrodes to a first cardiac site and a second cardiac site of a patient and electrically connecting the electrodes to a data collecting device. The device is then operated under a plurality of different cardiac conditions to obtain a plurality of different histogram data sets. Each of the plurality of the histogram data sets represents a cumulative time distribution

histogram of cardiac depolarization events detected at said second cardiac site in a plurality of cardiac beats. Mika clearly teaches as the cycle length of the patient's heart beats varies during the data collection time period depending on the state of exertion of the patient and since the detection sensitivity level is typically automatically changed by the pacemaker/ETC device the different histogram data sets will include at the end of the data collection period the cumulative time distribution histogram data for each unique data set. Mika teaches in figure 9 a schematic graph illustrating a typical cumulative distribution of cardiac cycle length. The horizontal axis represents the cycle length in milliseconds and the vertical axis represents the number of occurrences accumulated over the sampling period for a particular cycle length. The curve 121 represents a typical cycle length cumulative distribution curve which is well known in the art. The data for such a curve may be collected over a sampling period of a few hours or a few days. Note that Mika figure 10 teaches the steps of the method of updating the value of the logical variable ETC of FIGS. 8B-8C.It would have been obvious to one of ordinary skill in the art to generate in real-time the histogram data and the cumulative curve in Seely display in order to facilitate the indication and the precise evaluation of the medical measurement data with less user intervention.

As to claim 2, Seely et al teaches a method as claimed in claim 5, further including dynamically updating in real-time the histogram and the cumulative curve (These values can be displayed as pairs of dynamic variability parameter histograms 526, 546, figure 5).

As to claim 3, Seely et al teaches a method as claimed in claim 5, further including: filing the histogram is filled with measurement data from a time window advancing in real time with selectable fixed length (see figure 6, note that for each patient parameter v.sub.k, a user, typically

an attending physician, may select the number of data points m.sub.k to collect in order to perform the variability analysis).

As to claim 4, Seely et al teaches a method as claimed in claim 2, wherein, during the conversion, the computer generates aids for the retrospective analysis of histograms in the form of selectable functions that can be displayed on a viewing screen and outputs them together with the converted data combined as picture signals (note that the process 110 may be selected by a user from among a plurality of variability analysis options using a user interface 117, see paragraph [0061]).

As to claim 6, Seely et al teaches a method as claimed in claim 1, wherein the computer processes control signals that are produced by input means communicating with the computer and that serve to control the conversion and/or the output of the picture signals ,(The known individual patient interface and display 106a communicates measured values of the patient parameters to an apparatus in accordance with the invention that includes a processor 107 that performs individual patient data collection 108, paragraph [0061]) .

The limitation of claim 12 has been addressed in figure 5 of Seely, 502 and Mika paragraph [0012-0014]

Seely teaches the limitation of claim 14 wherein the retrospective analysis aids include a deviation readout (The simplest method for computing variability parameters involves the calculation of mean and standard deviation of the frequency distribution of a selected data set. This information can be updated continuously and displayed visually as a graph. Statistical

interpretation of the frequency distribution is dependent upon whether the distribution is normal or lognormal. There are standardized means of evaluating whether a distribution is accurately represented by a normal or log-normal curve, which include evaluation of kurtosis and skew. By calculating the kurtosis and skew, the user may be directed towards choosing an appropriate distribution. By evaluating the frequency distribution, the mean and standard deviation would represent the variability parameters for the particular patient parameter under evaluation, paragraph [0083])

Seely teaches the limitation of claim 15 in paragraph [0108]. Note that Mika teaches the generation of the cumulative curve in real time as the medical data is received (see paragraph [0165])

As to claim 16, Seely et al teaches the medical monitoring device as claimed in claim 15 further comprising an alarm indicator that is triggered measurement of histogram data is measured above or below a lower or upper alarm limits, (Alarms can be set so that if a variability histogram is within the normal range, it is displayed in one color (green, for example). If the value of the histogram rises above or falls below the normal range, it is displayed in a different color (red, for example), paragraph [0089]).

As to claim 17, Seely et al teaches the medical monitoring device as claimed in claim 13, wherein the histogram data is binned into histogram bins, the histogram bin size being definable by the user (The data is plotted in frequency bins, where each bin represents a proportional amount of variation, as measured by the squared difference from the mean, paragraph [0085]).

As to claim 18, Seely et al teaches the medical monitoring device as claimed in claim 13 further comprising display means for displaying real-time signal patterns of the medical measurement data (real-time display, 502, figure 5).

As to claim 19, Seely et al teaches the medical monitoring device as claimed in claim 18, wherein the real-time signal patterns and the histogram data are displayed next to one another on the display means (figure 5, 6; note that the variability analysis may be displayed on a multiple patient display at a central ICU console, as well as individual patient displays, paragraph [0108])

The limitation of claim 20-21, 24 and 26 has been addressed above. Note that Mika teaches the cumulative curve in figure 9 and Seely teaches the clinical therapeutic potential of this invention is the ability to distinguish pathologic from physiologic systemic properties by monitoring patterns of alterations in the variability of multiple patient parameters. Thus a display can be tailored to best represent the current state of any individual patient with a view to evaluating the physiologic and pathologic properties of individual organ systems, by following the variability of parameters intrinsic to that system. Moreover, Seely teaches the beneficial to distinguish between organ systems, because therapeutic intervention is commonly directed towards individual organs. Examples of organ systems include the cardiovascular system, respiratory system, the hematological system, central nervous system, liver and metabolic system, kidney and waste excretion system in order to provide flexibility in the display of variability of multiple parameters. The user may select various display options to profile an organ system or a combination of interdependent organ systems (paragraph [0091-0093]).moreover, Seely teaches retrospective analysis aids include a percentage of time that

histogram values are within limits defined by the range-selection cursors; a variability/stability readout that provides information about variability of the measurement data (Normal" ranges for the variability of each patient.

The limitation of claim 22 has been addressed in claim 5 (see also Mika et al. Abstract)

As to claim 25, Mika teaches the medical monitoring device includes a series of medical measurement values (The device is then operated under a plurality of different cardiac conditions to obtain a plurality of different histogram data sets. Each histogram data set represents a cumulative time distribution histogram of cardiac depolarization events detected at the second cardiac site in a plurality of cardiac beats, see abstract) and the cumulative curve includes a sum of the medical measurement values (paragraph [0161-0165])

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY BITAR whose telephone number is (571)270-1041. The examiner can normally be reached on Mon-Fri (7:30a.m. to 5:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jinge Wu can be reached on 571-272-7429. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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